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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/678,554	10/04/00	DOHERTY A	5604-D1-01-T

HM22/0518

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EXAMINER	
LUKTON, D	
ART UNIT	**PAPER NUMBER**
1653	5

DATE MAILED: 05/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/678,554	Doherty
Examiner	**Art Unit**
David Lukton	1653

-- Th MAILING DATE of this communication appears on the cov r sheet with the c rrespond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Mar 13, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-8 and 10-19 is/are pending in the applica

4a) Of the above, claim(s) 15-18 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-8, 10-14, and 19 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Applicants' election of Group I is acknowledged, as is the elected specie. Claims 15-18 are withdrawn from consideration at this time.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the two sequences on page 52.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application Serial No. 09/331876. Although the conflicting claims are not identical, they are not patentably distinct from each other. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on

this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11-14, 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown (pp. 52-56) that the compounds of examples 1-8 exhibit some propensity to inhibit ras farnesyl transferase *in vitro*. It is stipulated that the following claims are enabled:

> *A method of inhibiting ras farnesyl transferase in a mammal in need thereof comprising administering to said mammal a compound of claim 1 for a time and under conditions effective to inhibit ras farnesyl transferase.*
>
> *A method of inhibiting ras farnesyl transferase in a mammal afflicted with restenosis, cancer or psoriasis comprising administering to said mammal a compound of claim 1 for a time and under conditions effective to inhibit ras farnesyl transferase.*

Certainly also, an argument can be made that either of the following is enabled:

> *A method of inhibiting growth of tumor cells in a tumor-bearing mammal comprising*

administering to said mammal a compound of claim 1 for a time and under conditions effective to inhibit ras farnesyl transferase.

A method of inhibiting smooth muscle proliferation in a mammal which has been subjected to injury of vascular tissue comprising administering to said mammal a compound of claim 1 for a time and under conditions effective to inhibit ras farnesyl transferase.

However, claim 1 employs (last two lines) the terms "pharmaceutically" and "prodrugs". These terms carry with them the implied assertion that the compounds can be used therapeutically. This would include treatment of cancer, restenosis and atherosclerosis. As indicated above, it may well be the case that the underlying biochemical processes can be inhibited. But the question is whether the degree of inhibition is sufficient to be of benefit. The degree to which farnesyl transferase will be inhibited *in vivo* by a particular compound cannot be predicted merely be viewing the structure of the compound. Indeed, applicants have encountered variability in the degree of inhibition *in vitro*; these results could not have been predicted merely by viewing structures of compounds. In addition, it is not established that the IC50 value of even the best inhibitor is sufficiently low to be effective in the treatment of a given disease in a mammal. Another question is that of the degree of criticality of the farnesyl transferase to the cell proliferation process. Even if e.g., 90% of the enzyme activity could be blocked, would that be sufficient? It is suggested that the terms "pharmaceutically" and "prodrugs" be deleted from claim 1, and that the term "pharmaceutical" be deleted from claim 19.

*

Claims 1-8, 11-14, 19 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to "compounds" in the plural. However, applicants are claiming single compounds, rather than mixtures of compounds. Accordingly, the term "compound" should be used in the singular. Moreover, the dependent claims recite "compound" in the singular.
- The dependent claims recite "a compound". However, the definite article ("the") should be used instead, since the compounds that are referred to have already been identified.
- Claim 19 makes reference to a composition. However, a composition must have two components. Either or both of the following is suggested:

  A composition comprising a compound according to claim 1, and a carrier.

  A composition comprising a suitable carrier, and a compound according to claim 1 in an amount effective to inhibit ras farnesyl transferase.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800